

August 22, 1998

FDA Dockets Management Branch
(HFA-305) Food & Drug Administration
Attn: Michael Friedman, M.D.
Lead Deputy Commissioner
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

21 C.F.R. Part 101/Docket #98N-0044

Dear Dr. Friedman:

RE: Proposed FDA Regulations 21 C.F.R. 101.93 (II) (B);
21 C.F.R. 101.93 (I);
21 C.F.R. 101.93 (g) (2) (ii), (v), (vi), (vii), (viii)

I want you to know that I totally oppose the enacting into law the above-mentioned regulations proposed by the Food and Drug Administration regarding dietary supplements. Under these regulations:

Claims for states/symptoms not typically considered "diseases," such as aging, pregnancy and menopause, would be prohibited for dietary supplements, even where there is scientific substantiation to support them.

A dietary supplement for which only structure/function claims are made in the label or labeling in accord with section 403 (r) of the act may nevertheless be subjected to regulation as a drug if the agency has other evidence that the intended use of the product is for the diagnosis, cure, mitigation, treatment, or prevention of a disease.

Labeling of dietary supplements could not refer to or cite titles of publications (including scientific journals) in labeling of dietary supplements if the title mentions a disease.

Representations that a dietary supplement is useful to supplement drug therapy or has any role in the body's response to a disease would be prohibited (even where there is scientific support).

I recognize that appropriate agency guidance on the use of structure/function claims is necessary; however, the proposed regulations go beyond public protection. It is essential that we have access to valuable information on vitamins, minerals, and herbs regarding the maintenance of wellness and the prevention of disease.

I urge you to reconsider and revise these proposed regulations so that we can continue to receive valuable information necessary to make well-informed health decisions.

Sincerely,

Mary Knoblich
98N-0044

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